

REMARKS

Favorable reconsideration of this application, in light of the preceding amendments and following remarks, is respectfully requested.

Claims 1-17 are pending in this application.

Foreign Priority

Applicants note with appreciation the Examiner's acknowledgement that certified copies of all priority documents have been received by the U.S.P.T.O.

Examiner Interview

Initially, Applicants wish to thank the Examiner for the courtesies extended to Applicants' representative during the telephonic interview of July 6, 2010. The parties discussed the Boru reference as well as amendments to overcome Boru (§ 102 rejection) and the § 112 rejections. Specifically, the parties discussed amendments to relate the claimed "selection criterion" and the claimed "secondary selection criterion" together in claim 1. The parties discussed example embodiments to develop the aforementioned relationship. Applicants have amended the claims to be consistent with the Examiner interview. No agreement was made as to the specificities of claim amendments.

Rejections under 35 U.S.C. § 112

Claims 1-17 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants have

amended claims 1 and 6 taking into consideration the Examiner's comments made in the current office action and the aforementioned Examiner interview.

The Applicants, therefore, respectfully request reconsideration and withdrawal of the rejection to claims 1-17 under 35 U.S.C. § 112, second paragraph.

Rejections under 35 U.S.C. § 102

Claims 1-17 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. Pub. No. 2002/0077853 to Boru et al. ("Boru"). Applicants respectfully traverse this rejection for the reasons detailed below.

The Examiner asserts that the method of selecting a clinical trial as disclosed by Boru teaches the claimed method for "selecting a potential participant for a medical study," as recited by claim 1. Applicants respectfully disagree. Further, Applicants have amended the claims as discussed above in the Examiner interview.

Boru teaches facilitating identification of the most appropriate clinical trials by employing the "Exclusionary Criteria" already listed in the public clinicaltrials.gov site. The system searches a database of clinical studies, such as the clinicaltrials.gov database, to find the trials specific to a particular disease. All of the clinical trials in the disease-specific area are then extracted from the database. Next, all of the "exclusionary criteria" listed in each trial are then identified and extracted. After identifying all of the criteria cumulatively across all of the clinical trials, a list is made of the criteria having the most

redundancy, i.e., the criteria that are common to a predetermined number of the trials. See Boru paragraphs [0017]-[0020].

Boru teaches a system and method for use by a physician and a patient to create a list of clinical studies the patient may be suited for. The search results in a list of a few remaining studies applicable to the special patient. One of the studies can then be selected for the patient.

Further, Boru teaches the selection of a single "Exclusionary Criteria" based on choosing "common categories" into which similar criteria, although having different English language descriptions, may be sorted. Boru teaches that there may be some ambiguity in the searchable data, and that the physician may have to modify the search term. However, the modified search term is just the original term reworded. See Boru paragraph [0038]. Boru does not teach or fairly suggest "determining one or more **secondary criterion based on the selection criterion**" and "assigning the one or more secondary criterion to the selection criterion such that the **one or more secondary criterion are distinct from the selection criterion**," as required by claim 1. By contrast, Boru teaches a traditional process of **finding a few fixed exclusion criteria** which are common to possibly all or most of the studies in the clinicaltrials.gov database and to summarize these criteria in a short check list. The physician fills in the answers to the check list for the special patient. The search results in a list of a few remaining studies applicable to the special patient. One of the studies can then be selected for the patient.

For at least the reasons described above, Boru does not teach or fairly suggest each and every limitation of claim 1. Because Boru does not teach

each and every limitation of claim 1, Boru does not anticipate or render claim 1 obvious. Claims 2-17 are patentable at least by virtue of their dependency from claim 1.

The Applicants, therefore, respectfully request reconsideration and withdrawal of the rejection to claims 1-17 under 35 U.S.C. § 102(b).

Rejections under 35 U.S.C. § 103

Claims 6, 12, 13 and 14 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Boru in view of official notice. Applicants respectfully traverse this rejection for the reasons detailed below.

Claim 6 has been amended such that “a probability value of 100% or 0% is determined based on **other than the patient data stored in the database.**” Therefore, the Examiner’s broad reading of claim 6 is moot and the official notice regarding the use of a random number generator is not applicable. Claim 6 is patentable at least for this reason as well as its dependency from claim 1. Claims 12, 13 and 14 are patentable for reasons somewhat similar to those discussed regarding claim 6, noting that claims 12, 13 and 14 should be interpreted solely based on the limitations set forth therein.

The Applicants, therefore, respectfully request reconsideration and withdrawal of the rejection to claims 6, 12, 13 and 14 under 35 U.S.C. § 102(b).

CONCLUSION

In view of the above remarks and amendments, the Applicants respectfully submit that each of the pending objections and rejections has been addressed and overcome, placing the present application in condition for allowance. A notice to that effect is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to contact the undersigned.


Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

HARNESS, DICKEY, & PIERCE, P.L.C.

By


Donald J. Daley, Reg. No. 34,313
P.O. Box 8910
Reston, Virginia 20195
(703) 668-8000

DJD/EPs:lfb

958961.1